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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/505,458 02/11/00 ROSEN

M 61020-A/HOW/

EXAMINER

QM12/0313

Cooper & Dunham LLP
1185 Avenue of the Americas
New York NY 10036

ART UNIT PROPEZA F PAPER NUMBER

3762
DATE MAILED:

03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/505,458

Applicant(s)

ROSEN ET AL.

Examiner

Frances P. Oropeza

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3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Acknowledgement

1. Receipt is acknowledged of a preliminary amendment received 4/13/2000, which papers have been placed of record in the file.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Abstract

3. The abstract of the disclosure is objected to because of the language "said". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. Correction is required. See MPEP § 608.01(b).

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Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 9, 24, 28, 43, and 47 are ^{re}objected to because of the following informalities: Jef
5/2/01

- In claim 5, it is unclear if “a heart “ is the same “a heart” of claim 1,
- In claims 5 and 9, it is unclear if “an epicardial surface” is the same “an epicardial surface” of claim 1,
- In claim 24, it is unclear if “a heart “ is the same “a heart” of claim 20,
- In claims 24 and 28, it is unclear if “an epicardial surface” is the same “an epicardial surface” of claim 20,
- In claim 43, it is unclear if “a heart “ is the same “a heart” of claim 39, and
- In claims 43 and 47, it is unclear if “an epicardial surface” is the same “an epicardial surface” of claim 39.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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6. Claims 1, 2, 9-13, 20-21, 28-32, 39-40, and 47-51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Knisley (US 5824028). Knisley discloses a method and device with electrode(s) oriented relative to cardiac fiber direction whereby the stimulation pulse reduces the non-uniformity of the transmembrane voltage change associated with arrhythmic conditions.

The invention includes an electrical pulse generator (26), a lead assembly (25), and a plurality of linear electrodes (12). This invention focuses on the transmembrane potential and ion channels (column 1, lines 11-54) and recognizes the impact of treatment on the refractory period (column 3, lines 43-49). The electrode can be inserted in the myocardium, positioned to contract the epicardium or endocardium, or be a flat ribbon (column 2, lines 31-46). Sutures (column 2, line 66 – column 3, line 2) can attach the electrode. Alternate leads and electrode combinations are discussed to optimize polarity, timing and waveform shape (column 3, line 23-34).

7. Claims 1, 10-12, 20, 29-31, 39, and 47-50 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kroll et al. (US 5366485). Kroll et al disclose a defibrillation pretreatment of a heart, where a train of pulses are applied a fibrillating heart to organize the action of the chaotically contracting myocardial cells. The pretreatment system includes a power unit (12), conductors (14), and epicardial patches (16 and 18). The goal of the pretreatment is to increase the spatial organization of cells in the cardiac muscle (column 6, lines 34- 53). The pretreatment pulses address the heart-cell functions including the ion-pump mechanism, the voltage of the body fluid around the cells, the myocardial cell membrane and the refractory period (column 4, lines 46 – column 5, line 45). The pretreatment pulse can be varied relative to timing, length, height, polarity, pacing, and waveform (column 12, lines 10-25). The use of patch, subcutaneous

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or endocardial electrodes with the pretreatment system is disclosed (column 7, lines 43-47). The use of multiple electrode pairs is disclosed (column 2, lines 19-22).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 3, 7-8, 14, 17-19, 22, 26-27, 33, 36-38, 41, 45-46 and 52, 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knisley (US 5824028) in view of Dahl et al (US 5203348). As discussed in paragraph 6 of this action, Knisley discloses the claimed invention except for:

- the electrode strip of polyurethane (claims 3, 14, 22, 33, 41, and 52),
- the electrode comprised of platinum or consisting essentially of unalloyed platinum (claims 7-8, 17-18, 26-27, 36-37, 45-46, 55-56), and

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- the electrode connected to an insulated stainless steel wire (claims 19, 38, and 57).

Dahl et al disclose an electrode and teaches that it is known to fabricate an electrode with a platinum or platinum alloy conductor or conductor with a stainless steel core (column 20-36), and a lead with a medical grade polyurethane sheath and a stainless steel coated conductor (column 5, lines 23-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode and lead as taught by Knisley, with the materials of construction as taught by Dahl et al.. One have ordinary skill in the art would have been motivated to make such a modification in electrode and lead to gain improved electrical properties.

10. Claims 4-6, 15-16, 23-25, 34-35, 42-44, and 53-54 rejected under 35 U.S.C. 103(a) as being unpatentable over Knisley (US 5824028) and Dahl et al (US 5203348) in view of Ideker (US 5873893). As discussed in paragraphs 6 and 9 of this action, modified Knisley discloses the claimed invention except for:

- the electrode strip dimensions being about 7cm x 1 cm, (claims 4, 23, and 42),
- the electrode pairs arranged in two columns (claims 5, 15, 24, 34, 43, and 53), and
- the electrode pair being about 2 mm apart and the electrode pairs being about 5 mm apart (claims 6, 16, 25, 35, 44, and 54).

Ideker discloses a cardiac device for reducing arrhythmia and teaches that it is known to use an electrode configuration of an elongated primary strip having a plurality of electrodes positioned at spaced intervals, e.g. 1-4 millimeters (column 3, lines 2-4), along its length. While this reference shows the electrode pairs oriented parallel to the longer axis of the strip, it would be an obvious design choice to orient the electrode pairs perpendicular to the longer axis the strip. The

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length of the electrode strip and specific electrode spacing is also seen as an obvious design choice based on the specific situation and treatment plan. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode as taught by the modified Knisley device, with the elongated primary strip as taught by Ideker. One having ordinary skill in the art would have been motivated to make such a modification in electrode to gain a more focused area for electrical stimulation.

Other Prior Art Cited

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5871505 to Adams et al. teaches negative waveforms and dual capacitors. US 5814079 to Kieval teaches anodal stimulation. US 511811 to Smits teaches electrodes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO

[Signature]
JEFFREY R. JASTRZAB
PRIMARY EXAMINER
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